

DOLOGESIC NF- acetaminophen, dextbrompheniramine maleate tablet
Llorens Pharmaceutical International Division

Llorens-Dologesic 001

Active Ingredients

(in each caplet)

Acetaminophen 500 mg

Dextbrompheniramine Maleate 1 mg

Purpose

Pain reliever/fever reducer

antihistamine

Uses

- For the temporary relief of minor aches and pains associated with
- headache
- muscular aches
- backaches
- minor arthritis pain
- common cold
- toothaches
- menstrual cramps
- temporarily reduces fever
- itchy and watery eyes due to hay fever

Warnings

Alcohol Warning: If you consumer 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.

Liver Warning: This product contains acetaminophen. Sever liver damage may occur if you take

- more than 8 capsules in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product
- May cause drowsiness:: alcohol, sedatives and tranquilizers may increase the drowsiness effect.
- Avoid alcoholic beverages while taking this product
- Do not take this product if you are taking sedatives or tranquilizers, without consulting your doctor.
- Use caution when driving motor vehicle or operating machinery

Do not use

- with any other drug containing acetaminphen (prescription or non-prescription). If you are not sure whether a drug contains acetaminphen ask a doctor or pharmacist
- if you are allergic to acetaminophen or any of the inactive ingredients in the product
- for more than 10 days for pain, unless directed by a doctor
- for more than 3 days for fever, unless directed by a doctor

Ask a doctor before use:

- if you have liver disease
- if you are taking the blood thinning drug warafin

Stop using this product and ask a doctor if:

- pain gets worse or last more than 10 days
- fever gets worse or last more than 3 days
- new symptoms occur
- redness or swelling is present
- these could be signs of a serious condition

Keep out of reach of children

If you are pregnant or breast-feeding, ask a health professional before use.

Directions

Overdose Warning: Taking more than recommended dose (overdose), may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Do not exceed recommended dosage

Age	Dose
adults and children 12 years of age and over	Take 2 caplets every 4-6 hours. Do not take more than 8 caplets in 24 hours, or as directed by a doctor
children under 12 years of age	Do not use in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminphen and could cause liver damage

Inactive ingredients

FD&C Red #40, FD&C Yellow #6, glycerin, hydroxypropyl methyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, talc, titanium dioxide, tricalcium phosphate

Questions or comments

1-866-595-5598

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen.....	500 mg	Pain Reliever/Fever reducer
Dexbrompheniramine Maleate.....	1 mg	Antihistamine

Uses ■ For the temporary relief of minor aches and pains associated with ■ headache ■ muscular aches ■ backaches ■ minor arthritis pain ■ common cold ■ toothaches ■ menstrual cramps ■ temporarily reduces fever ■ itchy and watery eyes due to hay fever.

Warnings:
Alcohol Warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers.
Liver Warning: This product contains Acetaminophen. Severe liver damage may occur if you take ■ more than 8 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product ■ May cause drowsiness: alcohol, sedatives and tranquilizers may increase the drowsiness effect. ■ Avoid alcoholic beverages while taking this product ■ Do not take this product if you are taking sedatives or tranquilizers, without consulting your doctor. ■ Use caution when driving motor vehicle or operating machinery

Do not use ■ with any other drug containing acetaminophen (prescription or non-prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist ■ if you are allergic to acetaminophen or any of the inactive ingredients in the product ■ for more than 10 days for pain, unless directed by a doctor ■ for more than 3 days for fever, unless directed by a doctor.

Ask a doctor before use:
 ■ if you have liver disease ■ if you are taking the blood thinning drug warfarin. →



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 Llorens Pharmaceutical

NDC 54859-001-01

DOLOGESIC

ACETAMINOPHEN DEXBROMPHENIRAMINE MALEATE

SUGAR FREE

• ANALGESIC
• FEVER REDUCER

www.Llorensparm.com



100 CAPLETS

Drug Facts (continued)

Stop using this product and ask a doctor if:
 ■ pain gets worse or lasts more than 10 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present ■ These could be signs of a serious condition.

Keep out of reach of children.
Overdose Warning: Taking more than recommended dose (overdose), may cause liver damage. In case of accidental overdose, contact a physician or Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
If you are pregnant or breast-feeding, ask a health professional before use.

Directions: Do not exceed recommended dosage

Age	Dose
adults and children 12 years of age and over	Take 2 caplets every 4-6 hours. Do not take more than 8 caplets in 24 hours, or as directed by a doctor.
children under 12 years of age	Do not use in children under 12 years of age. This will provide more than the recommended dose (overdose) of acetaminophen and could cause liver damage.

Other information • store at room temperature 15° - 30°C (59° - 86°F).
 Tamper evident: Do not use if there is evidence of tampering.

Inactive ingredients: fd&c red 40, fd&c yellow 6, glycerin, hydroxypropyl methyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, talc, titanium dioxide, tricalcium phosphate.

Questions or Comments? 1-866-595-5598
Manufactured for: Llorens Pharmaceutical International Division, Inc., Miami, FL 33147

L-19
Rev. 03/23

DOLOGESIC NF

acetaminophen, dexbrompheniramine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54859-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	LLORENS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-001-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	
2	NDC:54859-001-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/01/2016	

Labeler - Llorens Pharmaceutical International Division (037342305)

Revised: 12/2025

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